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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,618	09/25/2003	Stephen T. Flock	D6476	6784

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EXAMINER
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HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/670,618

Applicant(s)

FLOCK ET AL.

Examiner

Michael J. Hayes

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8-32,34-37,43,44,50,51,61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8-32,34-37,43,44,50,51,61 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling how a material, such as polypyrrol, filings, or Nitinol functions as a means for driving an abrasive member at high frequencies.

With respect to claim 13, the specification does not enable a drive means that drives an abrasive member via piezoelectric material and with electrophoretic means. It appears that another drive means must be recited in the claims comprising the limitations of claim 13. Currently the claims appear to recite that one drive means performs both high frequency driving of the abrasive member and the electrophoretic process.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 6, 8, 14, 18, 19, 20-26, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by SUROFF (US Patent No. 5,150,492). Suroff discloses a device for altering tissue comprising an abrasive member contacting abrasive material on tissue or thereon and means to drive the member at high frequency. The device is capable of use with various tissues and various lubricant (i.e., water) and pharmaceuticals.

Claims 1, 2, 4-6, 8, 13-18, 20-26, and 62 are rejected under 35 U.S.C. 102(a) as being anticipated by BERNAZ (WO 02/053046) (See US Pub. No. 2004/0092959 for English version). Bernaz discloses a device for altering or ablating tissue comprising an abrasive member contacting abrasive material on tissue or thereon, electro or magneto responsive material (motor) means to drive the abrasive member at high frequency, abrasive material of aluminum oxide 50-90 microns, lubricant comprising water, and electrophoretic driving means. See 2004/0092959 paragraphs 0019, 0025, 0031, 0032, 0046-0047, 0052, 0055, 0062, and 0063. The device is capable of use with various tissues and pharmaceuticals.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 28, 34, 35, 36, 37, 50, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ as applied to claims 26 and 1 above, and further in view of

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EGGERS (US Patent No. 6,066,134). Bernaz discloses the claimed invention except for monitoring feedback using an electrical property of the tissue with the device, crystallized pharmaceutical, and monitoring feedback about a thermal property of the tissue. Eggers teaches monitoring feedback using a heartbeat and a thermal property of the tissue to perform a safe ablation procedure. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Eggers in the device of Bernaz to increase the safety of the ablation procedure for better patient outcome.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ as applied to claim 20 above, and further in view of UNGER (US Patent No. 6,416,740). Bernaz discloses the claimed invention except for a reservoir with a permeable membrane to release a pharmaceutical to the tissue. Unger teaches the use of a permeable membrane to release the pharmaceutical in a patch applied to the skin of a patient (see 69:11-14). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Unger in the device of Bernaz in order to provide a convenient patch for drug delivery through the skin after abrasion.

Claims 19, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ as applied to claim 1 above, and further in view of MELBOUCI et al. (US Patent No. 6,562,090). Bernaz discloses the claimed invention except for using a lubricant of water and glycerol with the abrasive. Melbouci teaches using water and glycerol with a lubricant to provide a stabilized suspension of abrasive in lubricant (see claim 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Melbouci in the device of Bernaz in order to facilitate the use of the abrasive.

Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ as applied to claim 1 above, and further in view of WEAVER. Bernaz discloses the claimed invention as discussed above but does not teach control means to monitor an fluorescence or reflectance of the tissue comprising radiant source, detector, and controller. Weaver teaches the use of control means to monitor tissue fluorescence or reflectance to facilitate ablation (see paragraphs 19, 34, 47, 58, 59, 104-112, 115, and 128). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Weaver in the invention of Bernaz in order to safely ablate tissue.

### ***Response to Arguments***

Applicant's arguments with respect to the previous rejections over the prior art are moot in view of the new rejections above, made in response to Applicant's claim amendments.

Applicant argues that magnetic filings, nitinol, and polypyrrol are known in the art to have medical applications. (Response pg. 9, 3<sup>rd</sup> Para.). The examiner agrees that these materials are known in the medical arts. However, the examiner does not agree that the use of these materials as a high frequency driver is enabled by Applicant's specification. The claims broadly recite the use of these materials as a high frequency driver, the inventor provides no direction or working examples in using them as a high frequency driver, and no prior art addressing such use has been provided by Applicant. In view of these considerations, the examiner maintains that the specification is not enabling for how a material, such as polypyrrol, filings, or Nitinol functions as a means for driving an abrasive member at high frequencies.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (703) 308-2698. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh  
18 February 2005

A handwritten signature in black ink, appearing to read "M J Hayes", with a long horizontal flourish extending to the right.

**MICHAEL J. HAYES  
PRIMARY EXAMINER**